Remarks

Claims 48-54 are presented.

35 USC §112 - Written Description

Claims 48-54 have been rejected for an alleged failure of written description. The Office Action states that there is no support for "a second pressure above ambient and less than the first elevated pressure." The rejection is traversed.

That the second pressure is less than the first pressure is expressly taught at page 4 lines 17-18. This feature was also recited in original claim 1.

Claim 48 has been amended to remove "above ambient and." Entry of the amendment to claim 48 after Final Rejection is proper because it removes the written description ground for rejection of claims 48-54 and the rejection was not presented to the applicant before the Final Rejection. The applicant believes that there is support for the deleted term, however the term is being removed to moot the rejection. Consequently the written rejection of claims 48-54 should be withdrawn.

35USC §103(a) - Obviousness

Claims 48-54 have been rejected as obvious from Hamilton (US 5797877), taken with Anderson (US 5500180). The rejection is traversed.

This is a new ground of rejection which applicant is not previously had an opportunity to respond. Accompanying this Amendment are Declarations of Greg Mitchell and Jeffery Bruce attesting to commercial success of commercial balloons derived from pre-sterilized balloons as presently claimed, and to the nexus between the of the pre-sterilization shrinkage step and the final balloon compliance which in turn is responsible for the commercial success. As applicant has not previously had an opportunity to respond to the outstanding rejection, submission of these declarations after Final Rejection is seen to be proper. Entry and consideration of the declarations is therefore respectfully requested.

Certain details of the applicant's process and market share are considered proprietary and have been submitted in confidential supplements to the respective declarations. Supplements are seen to be exempt from disclosure under the FOIA and it is respectfully requested that the

USPTO treat them as such under the provisions of FOIA exemption 4 (5 U.S.C. 552(b)(4)), and 37 CFR §102.9.

Claim 48 defines a medical balloon. However, at the time window defined in the claim it has not yet been sterilized. The balloon is made of a block copolymer and has been produced by a process that included a shrink step. That shrink step has already occurred at the time window defined in claim 48. The product, claimed at that time, is unquestionably both novel and non-obvious over the cited patents.

Hamilton, which is commonly owned with the present application, teaches balloons made from thermoplastic elastomers. The thermoplastic elastomer may be a block copolymer such as a Hytrel® polymer. Hamilton does not mention a shrink step, much less a pre-sterilization shrink step.

Anderson also describes balloons made from a block copolymer. Anderson teaches that sterilization can cause loss of balloon properties during a traditional sterilization. This can be avoided if the specific sterilization steps are employed. Anderson also does not teach to utilize a shrink step before sterilization.

Therefore neither of the cited patents teaches or suggests producing a pre-sterilized balloon using a shrink step.

In the decision on the earlier appeal in this case, the Board of Patent Interferences and Appeals relied on Anderson's sterilization step as the basis for affirming the Examiner's anticipation rejection of previous claim 11, specifically attributing to Anderson's sterilization step as "reasonably assessed as effecting a degree of shrinking" (Paper 31, page 10).

Claim 48 clearly avoids the basis for the prior decision by looking at the balloon at a window of time before sterilization. At that same stage there is absolutely no basis to assert that any step of Anderson's balloon processing could reasonably be assessed as "effecting a degree of shrinking."

Anderson clearly teaches away from using shrinkage as a balloon forming technique since it teaches that the balloon properties Anderson wants will be lost unless its particular low temperature, low humidity, sterilization process is used. Col. 10, lines 38-65, col. 11, lines 5-10. Nothing anywhere in Anderson indicates that a post-formation, pre-sterilization, shrinking step would be of benefit in a balloon formation process. Moreover, Anderson's stated criticality in

controlling sterilization conditions clearly would have lead one to believe that performing a deliberate shrinking step prior to sterilization could not produce a "clinically useful and safe finished balloon." See Anderson col. 11, lines 5-7.

Contrary to the expectation created by the Anderson patent, the claimed balloons are useful. The benefit of the pre-sterilization shrink step carries through to the final sterilized balloons [Mitchell Declaration ¶¶ 5-9], so much so, that the owner of the application has introduced a new line of catheters (C•R•E™) whose balloons are obtained from balloons as recited in claim 48. The balloons have been extremely successful in the gastrointestinal market, a success which is directly related to the high compliance characteristics of the balloons [Bruce Declaration]. At the time they were introduced, most of the C•R•E™ balloons could not have been produced with these compliance characteristics, without using a pre-sterilization shrinking step [Mitchell Declaration ¶10]. The comparative data in Mitchell Declaration ¶¶ 5-9 demonstrates that this line of balloons could not have been produced merely by using sterilization conditions that merely accomplished "a degree of shrinkage, as could by generated during sterilization."

The pre-sterilization step increases manufacturing cost and the company has been trying to eliminate it, but so far an alternate process has not been qualified for the majority of balloon sizes that use pre-sterilization shrinking [Mitchell Declaration ¶4]. The commercial success of the C•R•E™ balloon catheters is directly tied to the high compliance of the balloons which in turn depends on the pre-sterilization shrinking. In view of this evidence which demonstrates a nexus between the pre-sterilization shrinking and the great commercial success of the balloon catheters on which they are subsequently deployed, a finding of non-obviousness is required. *In re Sernaker* 217 USPQ 1 (Fed. Cir. 1983).

Neither Hamilton nor Anderson contemplate shrinking a formed balloon at the relevant point in time defined in claim 48, *i.e.* before sterilization. The pre-sterilization effect on final balloon compliance adds to any compliance modification that is obtained in sterilization and so sterilization is not an equivalent step. The claimed balloons are non-obvious over the cited patents. The skilled person is given no motivation to produce such a balloon that is shrunk before sterilization and Anderson gives strong reason to believe it would be harmful. To the contrary, pre-sterilization shrinking produces a unique and non-obvious balloon whose

commercial success objectively demonstrates non-obviousness. Withdrawal of the rejection on Hamilton in view of Anderson is therefore respectfully requested.

Conclusion

The amended claims are supported by the written description and are non-obvious. Reconsideration and allowance are respectfully requested.

Respectfully submitted,

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